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BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **GOLDEN STATE PHARMACEUTICALS;** **KENNETH JACK AMODEO** **768 Calle Plano** **Camarillo, CA 93012** **Pharmacy Permit No. PHY 48647,** **Pharmacist License No. RPH 37646** Respondent.	Case No. 4801 **ACCUSATION**

Complainant alleges:

PARTIES

1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

2. On or about August 24, 2007, the Board of Pharmacy issued Pharmacy Permit Number PHY 48647 to Golden State Pharmaceuticals (Respondent). The Pharmacy Permit expired on August 1, 2010, and has not been renewed.

3. On or about April 4, 1983, the Board of Pharmacy issued Original Pharmacist License Number RPH 37646 to, Kenneth Jack Amadeo ("Respondent"). The Original Pharmacist License will expire on February 28, 2015, unless renewed.

JURISDICTION

4. This Accusation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

5. Section 4300 of the Code states:

"(a) Every license issued may be suspended or revoked.

"(b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:

"(1) Suspending judgment.

"(2) Placing him or her upon probation.

"(3) Suspending his or her right to practice for a period not exceeding one year.

"(4) Revoking his or her license.

"(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.

....

"(d) The board may initiate disciplinary proceedings to revoke or suspend any probationary certificate of licensure for any violation of the terms and conditions of probation. Upon satisfactory completion of probation, the board shall convert the probationary certificate to a regular certificate, free of conditions.

"(e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure."

6. Section 4300.1 of the Code states:

"The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license."

7. Section 4333 of the Code states, in pertinent part, that all prescriptions filled by a pharmacy and all other records required by Section 4081 shall be maintained on the premises and available for inspection by authorized officers of the law for a period of at least three years. In cases where the pharmacy discontinues business, these records shall be maintained in a board-licensed facility for at least three years.

8. Section 4081 of the Code states:

"(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

"(b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or representative-in-charge, for maintaining the records and inventory described in this section.

"(c) The pharmacist-in-charge or representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or representative-in-charge had no knowledge, or in which he or she did not knowingly participate."

9. Section 4059 of the Code states:

"(a) A person may not furnish any dangerous drug, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. A person may not furnish any dangerous device, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7.

...."

10. Section 4060 of the Code states:

"No person shall possess any controlled substance, except that furnished to a person upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7, or furnished pursuant to a drug order issued by a certified nurse-midwife pursuant to Section 2746.51, a nurse practitioner pursuant to Section 2836.1, or a physician assistant pursuant to Section 3502.1, or naturopathic doctor pursuant to Section 3640.5, or a pharmacist pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052. This section shall not apply to the possession of any controlled substance by a manufacturer, wholesaler, pharmacy, pharmacist, physician, podiatrist, dentist, optometrist, veterinarian, naturopathic doctor, certified nurse-midwife, nurse practitioner, or physician assistant, when in stock in containers correctly labeled with the name and address of the supplier or producer.

"Nothing in this section authorizes a certified nurse-midwife, a nurse practitioner, a physician assistant, or a naturopathic doctor, to order his or her own stock of dangerous drugs and devices."

REGULATIONS

11. California Code of Regulations, title 16, section 1770, states:

"For the purpose of denial, suspension, or revocation of a personal or facility license pursuant to Division 1.5 (commencing with Section 475) of the Business and Professions Code, a crime or act shall be considered substantially related to the qualifications, functions or duties of a licensee or registrant if to a substantial degree it evidences present or potential unfitness of a

licensee or registrant to perform the functions authorized by his license or registration in a manner consistent with the public health, safety, or welfare."

12. California Code of Regulations, title 16, section 1708.2 provides:

"Any permit holder shall contact the board prior to transferring or selling any dangerous drugs, devices or hypodermics inventory as a result of termination of business or bankruptcy proceedings and shall follow official instructions given by the board applicable to the transaction."

13. California Code of Regulations, title 16, section 1761 provides:

"(a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription.”...."

COSTS

14. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

FIRST CAUSE FOR DISCIPLINE

(Golden State Pharmaceuticals - Failure to File Discontinuance of Business)

15. Respondent Golden State Pharmaceuticals is subject to disciplinary action under title 16, section 1708.2 of the California Code of Regulations (CCR) in that Respondent failed to contact the Board prior to transferring or selling any dangerous drugs, devices or hypodermic inventory as a result of termination of its business. The circumstances are as follows:

16. On or about April 29, 2011, an onsite inspection by the Board of Pharmacy revealed that another business was operating out of the business address licensed to Respondent located at 768 Calle Plano, Camarillo, CA 93012. Respondent failed to submit or file a Discontinuance of Business form with the Board upon the termination of its business.

SECOND CAUSE FOR DISCIPLINE

(Golden State Pharmaceuticals - Failure to Maintain Prescription Records)

17. Respondent Golden State Pharmaceuticals is subject to disciplinary action under section 4333 in conjunction with 4081 of the Code in that it failed to maintain all prescriptions filled by the pharmacy and all other records on its premises for inspection by authorized officers for a period of three years. The circumstances are as follows:

18. On or about June 16, 2010 Respondent Golden State Pharmaceuticals terminated its business operations located at 768 Calle Plano, Camarillo, CA 93012, and subsequently failed to notify the Board prior to transferring, selling or disposing of all dangerous drugs and devices. In addition, Respondent failed to notify the Board as to where all records of acquisition and disposition of dangerous drugs, including prescription files, were retained and maintained for the legally required period of three years from the date of making.

THIRD CAUSE FOR DISCIPLINE

(Golden State Pharmaceuticals - Unauthorized Prescriptions)

19. Respondent Golden State Pharmaceuticals is subject to disciplinary action under title 16, section 1761, subdivision (a) of the CCR in conjunction with section 4059 subdivision (a) and 4060 of the Code in that it failed to contact the prescribers to validate prescriptions prior to compounding or dispensing such prescriptions which contained significant errors, omissions, irregularities, uncertainties, ambiguities, or alterations. The circumstances are as follows:

20. From on or about January 2009 to June 2010, Respondent Golden State Pharmaceuticals furnished and dispensed approximately 1000 controlled substance prescriptions, which were not prescribed or authorized by Douglas Mills, M.D.. Specifically, Respondent failed to obtain validation of the prescriptions from Dr. Mills who was not employed by Frontline Medical Associates, the prescribing medical group, since September 2007, and had not been practicing medicine in the State of California since October 2009.

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FOURTH CAUSE FOR DISCIPLINE

(Kenneth Jack Amodeo - Failure to Maintain Prescription Records)

21. Respondent Kenneth Jack Amodeo is subject to disciplinary action under section 4333 in conjunction with 4081 of the Code in that he failed to maintain all prescriptions filled by the pharmacy and all other records on its premises for inspection by authorized officers for a period of three years. The circumstances are as follows:

22. On or about June 16, 2010, while Respondent Kenneth Jack Amodeo was the Pharmacist-in-Charge, Golden State Pharmaceuticals terminated its business operations located at 768 Calle Plano, Camarillo, CA 93012. Respondent Amodeo failed to notify the Board of the termination of business practices prior to transferring, selling or disposing of all dangerous drugs and devices. In addition, Respondent Amodeo failed to notify the Board as to where all records of acquisition and disposition of dangerous drugs, including prescription files, were retained and maintained for the legally required period of three years from the date of making.

FIFTH CAUSE FOR DISCIPLINE

(Kenneth Jack Amodeo - Unauthorized Prescriptions)

23. Respondent Kenneth Jack Amodeo is subject to disciplinary action under Title 16, section 1761, subdivision (a) of the CCR in conjunction with section 4059 subdivision (a) and 4060 of the Code in that while he was the Pharmacist-In-Charge, the pharmacist(s) who dispensed the prescriptions failed to contact the prescribers to validate prescriptions prior to compounding or dispensing such prescriptions, which contained significant errors, omissions, irregularities, uncertainties, ambiguities, or alterations. The circumstances are as follows:

24. From on or about January 2009 to June 2010, Respondent Kenneth Jack Amodeo was the Pharmacist-In-Charge at Golden State Pharmaceuticals. During this time frame, approximately 1000 controlled substance prescriptions were furnished and dispensed, which were not prescribed or authorized by Douglas Mills, M.D.. Specifically, the pharmacist(s) failed to obtain validation of the prescriptions from Dr. Mills who was not employed by Frontline Medical Associates, the prescribing medical group, since September 2007 and had not been practicing medicine in the State of California since October 2009.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Pharmacy Permit Number PHY 48647, issued to Golden State Pharmaceuticals and PIC Kenneth Jack Amodeo.

2. Revoking or suspending Pharmacist license Number RPH 48647, issued to Kenneth Jack Amodeo;

3. Ordering Kenneth Jack Amodeo and Golden State Pharmaceuticals to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;

4. Taking such other and further action as deemed necessary and proper.

DATED: 1/6/14

VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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